IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 4 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DEFENSE EXPERT SAMANTHA J. PULLIAM, M.D.

Plaintiffs hereby seek to exclude certain opinions and testimony proffered by Defendants' expert Samantha J. Pulliam, M.D. (hereinafter "Dr. Pulliam"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

In the wave of cases listed in Exhibit A to Plaintiffs' motion, Defendants have designated Dr. Pulliam to offer a number of opinions that are beyond her expertise and/or that are unreliable, irrelevant, and/or otherwise improper. For the reasons set forth below, this Court should preclude Dr. Pulliam from providing the following:

1. Opinions regarding mesh cytotoxicity and degradation, including that polypropylene is the best material available, because such opinions are beyond her expertise and are unreliable.
2. Opinions regarding fraying and particle loss, because such opinions are unreliable and beyond her expertise;
3. Opinions regarding the Instructions for Use, because such opinions are beyond her expertise and are improper;

4. Opinions regarding training and teaching, because such opinions are beyond her expertise, unreliable, irrelevant, and improper; and,
5. Opinions constituting legal conclusions, because such opinions are improper expert testimony.

All of these opinions are inadmissible under the Federal Rules of Evidence and the *Daubert* standard governing expert witness testimony.

PRELIMINARY AND FACTUAL STATEMENT

Defendants have designated Dr. Pulliam to provide general expert opinions addressing TVT and TVT-O. *See* Ex. B, TVT and TVT-O Expert Report of Samantha J. Pulliam, M.D. (hereinafter "Expert Report") at 1. Dr. Pulliam is a urogynecologist in Chapel Hill, North Carolina. *See* Ex. C, Curriculum Vitae of Samantha J. Pulliam, M.D. (hereinafter "Pulliam CV"). Dr. Pulliam has performed approximately 700 mid-urethral sling procedures over the past 10 years. Ex. B, Expert Report at 3. Dr. Pulliam testified that, of those 700 procedures, approximately 680 utilized polypropylene mesh/sling devices. *See* Ex. D, a true copy of the 3/31/2017 deposition transcript of Samantha J. Pulliam, M.D. (hereinafter "Pulliam Dep. Tr.") at 118:8-24. Of those 680 procedures, 450 involved TVT while 120 involved TVT-O. *Id.* at 124:8-12. In other words, the number of procedures involving TVT or TVT-O, the two products for which she has been retained, totals approximately 570. Dr. Pulliam last implanted TVT in December 2015, *id.* at 125:10, and last implanted TVT-O three to four years ago, *id.* at 126:7-8. Of the 680 procedures utilizing polypropylene mesh devices, five to seven of those patients have returned to Dr. Pulliam for subsequent complications, *id.* at 129:8-20. Further, Dr. Pulliam has performed zero complete

explants of TVT and TVT-O, *id.* at 142:11-22, and only seven to eight revisions or partial explants of TVT and TVT-O,[1] *id.* at 143:11-24.

It is important to note that all numbers provided by Dr. Pulliam, including the number of implantation and revision procedures, are estimates because she has not maintained a database or otherwise followed her patients and the procedures she has performed. *Id.* at 116:23-117:22; 255:10-256:2. For instance, Dr. Pulliam originally arrived at her 700 mid-urethral sling procedure figure by estimating the number of procedures she performs in an average month multiplied by the number of months she has been practicing. *Id.* at 115:18-116:16. Indeed, Dr. Pulliam's 450 TVT figure is even more of a rough estimate:

> Q. Okay. Out of the 680 polypropylene mesh mid-urethral slings, a vast majority being Ethicon, I need you to tell me how many are TVT-R.
> A. So the TVT-R, probably -- I mean, since I've been here, I've done -- they didn't have the TVT-R here, and I've gone with the Exact. So if -- *let's just say for easy math, I did five a month since I've been here, and I do probably three-quarters of my slings as TVT Retropubic or TVT*, yeah, retropubic. *So let's say three quarters of 680 minus 60. That's 450 roughly*.

Id. at 120:7-17 (emphasis added); *see also id.* at 122:6-11 ("I'm doing my best to do math. This is not something that is included in my report, and *it's all something that I'm deriving off the top of my head* because this is not, again, something I based my general report upon in terms of the specific numbers.") (emphasis added).

Prior to being retained in this litigation, Dr. Pulliam never differentiated between mechanical cut and laser cut TVT, including never apprising herself of which cut she was implanting. Dr. Pulliam testified that: she has never documented whether she was implanting a

[1] Although Dr. Pulliam estimates that she has performed a total of 10-20 revisions or partial explants in her career, she could not say whether or not they were the two devices at issue in this litigation, and freely admitted as much. Ex. D, Pulliam Dep. Tr. at 135:2-5 ("And I have probably worked on, over the course of 10 years, probably 10 or 20 patients who I've removed mesh from [sic] a sling. I'm not sure I can say they're TVT. In fact, I can't.") (emphasis added). Thus, Plaintiffs are operating under the seven to eight revisions for which she knew the product was either TVT or TVT-O.

TVT laser cut or mechanical cut beyond what the specific device itself reflects in the medical records, *id.* at 127:14-22; she does not know how many laser cut versus mechanical cut TVT devices she has implanted, *id.* at 127:23-128:2; at the time of each implantation, she did not know whether the device was mechanical cut or laser cut and such knowledge was not important to her, *id.* at 128:21-129:3; of the five TVT patients who presented with complications, she does not know how many were implanted with mechanical cut TVT, *id.* at 130:13-18; of the five TVT revisions or partial explants she has performed, she does not know how many were mechanical cut versus laser cut, *id.* at 135:22-25; she has never followed the outcomes – in research, clinical trials, her practice or otherwise – of her patients who had mechanical cut TVT versus laser cut, *id.* at 145:14-22; she does not know whether she has ever seen a direct comparison of laser cut mesh to mechanically cut mesh "in any major study that would be meaningful to [her]," *id.* at 150:21-24; and, she has never examined a histopathological slide involving an explant mechanical cut TVT under a microscope, *id.* at 172:14-19.

ARGUMENT

In addition to specific legal citations and argument contained in this Memorandum, Plaintiffs incorporate by reference the standard of review for Daubert motions previously set forth in this litigation. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 692, 701 (S.D.W. Va. 2014).

I. Opinions regarding mesh cytotoxicity and degradation, including that polypropylene is the best material available, should be excluded because such opinions are beyond her expertise and are unreliable.

A. Cytotoxicity

Dr. Pulliam is not qualified to opine that prolene mesh and the TVT device are not cytotoxic. Dr. Pulliam states that "[p]rolene mesh is not cytotoxic," Ex. B, Exert Report at 15, and testified in her deposition that it is her opinion that TVT "is not cytotoxic," Ex. D, Pulliam Dep.

Tr. at 229:3-5. However, these opinions exceed Dr. Pulliam's expertise and qualifications. Dr. Pulliam is not a toxicologist, and her background is devoid of any experience translating laboratory cytotoxicity test results into clinical effect. *See generally* Ex. C, Pulliam CV. Moreover, Dr. Pulliam testified that: she has "never looked through a microscope to explanted mesh," Ex. D, Pulliam Dep. Tr. at 170:14-16; she did not check to see whether *any* of the estimated five TVT patients upon whom she performed a revision had a foreign body reaction to the mesh, *id.* at 179:5-18; she has never personally conducted any bench or laboratory research on polypropylene, *id.* at 216:4-6; and, she has never conducted studies on the properties of the mesh, *id.* at 216:7-10.

In *Huskey*, Ethicon argued that an expert's testimony regarding cytotoxicity exceeded his qualifications "because he does not have toxicological experience, and he admits that he has never conducted toxicity or cytotoxicity testing of mesh," but this Court found him qualified to opine that Ethicon failed to warn of the risk of cytotoxicity because even if "not a toxicologist, he stated that he regularly encounters cytotoxicity in his practice, including in women who have polypropylene mesh implants[,]" and "that he has removed mesh implants, including the TVT, as a result of cytotoxicity." *Huskey*, 29 F. Supp. 3d at 704–05; *see also Edwards*, 2014 WL 3361923, at *9 (same). Contrary to the expert in *Huskey* and *Edwards*, Dr. Pulliam did not list cytotoxicity as a complication that she has encountered in her clinical practice, Ex. D, Pulliam Dep. Tr. at 181:7-22 (listing mesh exposure, urinary retention, retropubic hematoma, and voiding dysfunction as the TVT complications she has encountered in her practice, and mesh exposure, urinary retention, voiding dysfunction, and transient thigh pain as the TVT-O complications she has encountered in her practice). Further, Dr. Pulliam testified that of the approximately five TVT revisions or partial explants she has performed, none were for cytotoxicity, *id.* at 164:24-165:23 (attributing three to mesh exposure), and, similarly, of the estimated two TVT-O revisions or

partial explants she has performed, none were for cytotoxicity, *id.* at 167:12-23 (attributing both to mesh exposure).

In sum, Dr. Pulliam is not qualified to opine as to cytotoxicity because she is not a toxicologist and her clinical practice is devoid of any experience in cytotoxicity, such as encountering cytotoxicity in her patients or removing mesh implants as a result of cytotoxicity.

Dr. Pulliam's cytotoxicity opinion should also be excluded as unreliable. In her report, Dr. Pulliam supports her cytotoxicity opinion with unidentified, disparate studies:

> Evaluation of implanted mesh has confirmed tissue ingrowth and a lack of inflammation. If the mesh were cytotoxic, one would expect the opposite, including tissue necrosis, mesh rejection, and failed incorporation of mesh by the surrounding tissues. This is not consistent with clinical studies showing excellent safety, tolerability, low levels of infection, and mesh erosion, and efficacy.

Ex. B, Expert Report at 15. Dr. Pulliam failed to provide more insight during her deposition, as she simply responded "[w]ell, there are the reviews that I cited in my expert report" when asked for the basis of the cytotoxicity opinion. Ex. D, Pulliam Dep. Tr. at 229:6-9.[2] Since Dr. Pulliam has neither identified the underlying evaluations and studies nor described her process or method for extrapolating these underlying, separate studies to ultimately conclude that prolene mesh is not cytotoxic, it is impossible to know not only the methodology and reliability of the underlying studies themselves, but also whether her extrapolation and analytical method was based on reliable methodology and the scientific method. Therefore, Dr. Pulliam's opinion regarding cytotoxicity should be excluded as unreliable. *See Konrick v. Exxon Mobil Corp.*, No. CV 14–524, 2016 WL 439361, at *13 (E.D. La. Feb. 4, 2016) ("Without any explanation of [the expert's] methodology

[2] The remainder of Dr. Pulliam's answer similarly fails to provide her basis as it is simply a restatement of the portion of her report excerpted above. *See id.* at 229:13-21 ("[C]ytotoxicity means that cells die. There's necrosis and tissue death around it. And that's just not what we see in 97 percentish of patients, give or take a few percentage points depending on which study you look at. Patients heal and they heal rapidly. So I think there was the idea of cell death as a result of the presence of the sling is really not borne out clinically.").

or application of her analytical methods to the literature, the report does not provide a reliable basis for [the expert's] opinion.").

B. Degradation

Dr. Pulliam also intends to opine "that the degradation of polypropylene mesh probably does not occur, but even if it does, there is no clinically significant impact." Ex. B, Expert Report at 15. As with her cytotoxicity opinion, however, Dr. Pulliam is not qualified to opine regarding degradation. Dr. Pulliam specializes in pelvic floor medicine and has implanted approximately 680 polypropylene mesh devices, Ex. D, Pulliam Dep. Tr. at 118:8-24, including 450 TVT and 120 TVT-O, *id.* at 124:8-12, but she has treated only five to seven of those 680 patients for subsequent complications, *id.* at 129:8-14. Further, she has performed zero complete explants of TVT and TVT-O, *id.* at 142:8-22, and only seven to eight revisions or partial explants of TVT and TVT-O, *id.* at 143:11-24. Moreover, Dr. Pulliam has never authored or published any peer-reviewed articles on degradation, nor has she ever spoken on degradation at any conference. *Id.* at 177:10-16. Although Dr. Pulliam claims to have seen photographs and micrographs of an explanted TVT sling, she testified that: she has never examined an explanted mesh in a non-image format, *id.* at 170:2-16; other than a macroscopic evaluation "just to basically affirm that [she] identified and removed mesh," she has never requested any kind of analysis of any TVT device that she has revised or partially explanted, *id.* at 171:7-12; she has never examined a histopathological slide involving explanted Prolene mesh under a microscope, *id.* at 172:2-13; she has never examined any histopathological slide involving explanted mechanical cut or laser cut TVT under a microscope, *id.* at 172:14-25; she has never examined any histopathological slide involving explanted TVT-O under a microscope, *id.* at 173:2-6; and, she has never made a histopathologic slide related to a polypropylene mesh post-explantation, *id.* at 173:8-17. In short,

Dr. Pulliam stands in contrast to previous physicians specializing in pelvic floor who have been deemed qualified by medical experience to opine as to degradation; and, assuming *arguendo* that the experience gained by implanting 450 TVT and 120 TVT-O devices qualifies her to opine to issues surrounding implantation, Dr. Pulliam has virtually no post-implantation experience – i.e., performing complete mesh explants, performing mesh revisions or partial explants, and examining mesh explants – that is related, or qualifies her to opine, to mesh degradation.

Even if qualified, Dr. Pulliam's opinion is unreliable. In her report, Dr. Pulliam states:

> [P]olypropylene mesh appears to remain effective over time, which suggests that degradation [sic] of the mesh does not occur. Clave (Int Urogynecol J. 2010 Mar;21(3):261-70) reported cracking of the surface of polypropylene mesh evaluated after explantation from patients. However, the mechanical properties of mesh and the possible damage to the mesh during its removal could not be evaluated. Given the excellent medium and long term results from slings (Ford et al., Cochrane Database Syst Rev. 2015 Jul 1;(7)), there is no evidence that the findings of Clave correspond to functional compromise.

Ex. B, Expert Report at 15. In other words, Dr. Pulliam identifies one study that reported cracking of the surface of polypropylene mesh evaluated after explantation, but then uses the "excellent medium and long term results" reported in a subsequent, unaffiliated review to summarily conclude that the former study's results do not correspond to functional compromise. *See id.*

However, said review expressly states that long term results, i.e., beyond five years after surgery, is a limitation of the review. *See* Ex. E, AA Ford et al., *Mid-urethral Sling Operations for Stress Urinary Incontinence in Women (Review)*, Cochrane Database of Systematic Reviews 2015, Issue 7, at 3. Specifically, under "Limitations of the review," the authors state that:

> At present there are only a limited number of randomised controlled trials (these produce the most reliable results) that have published data beyond five years after surgery. *This means that evidence about how effective and safe these procedures are in the longer term lags behind the evidence for them in the short and medium term (up to five years)*. We encourage researchers to publish longer-term data ***to help increase the reliability of longer-term results*** in this area.

Id. (emphasis added). Moreover, in a separate section under "Authors' conclusions," it states that "[a] salient point illustrated throughout this review *is the need for reporting of longer-term outcome data* from the numerous existing trials. This would substantially increase the evidence base and provide clarification regarding uncertainties about long-term effectiveness and adverse event profile." *Id.* at 2 (emphasis added). Indeed, "the long-term effects of surgery . . . *have not been established*" because "although 35 of the 81 trials included [in this review] should be in a position to report their long-term data (i.e. over five years), only three have done so." *Id.* at 48 (emphasis added). In short, Dr. Pulliam applies the allegedly excellent long term results of a review to an unaffiliated study in order to reach a conclusion that supports her opinion, but the very authors of said review affirmatively state that longer-term data is a limitation of the review, that more longer-term data must be published "*to help increase the reliability of longer-term results*," that evidence regarding efficacy and safety in the longer-term lags behind the evidence for them in the short and medium term, and that the "*long-term effects . . . have not been established*." *Id.* at 2, 3, 48 (emphasis added). Hence, the review is not a reliable basis from which to extrapolate longer-term results regarding efficacy and safety; and, certainly, such extrapolation is even more unreliable when applied to a prior, unrelated study to reach a conclusion (i.e., surface cracking does not correspond to functional compromise) said study did not originally reach.

Additionally, this opinion is unreliable because Dr. Pulliam fails to provide sound basis for the central premise or hypothesis she uses to reach and support her opinion, thereby constituting unreliable methodology. Dr. Pulliam's opinion is premised upon her hypothesis that "polypropylene mesh appears to remain effective over time, which suggests that degradation [sic] of the mesh does not occur." Ex. B, Expert Report at 15. In other words, that polypropylene mesh allegedly remains effective over time proves that mesh degradation *in vivo* does not occur.

However, Dr. Pulliam neither identifies nor explains the basis, process or method by which she formulated this hypothesis. Similarly, Dr. Pulliam fails to explain inherent gaps of this hypothesis. For example, to be operable, this premise or hypothesis inherently presupposes that (i) mesh efficacy is the sole suggestion or indicator that degradation occurs, (ii) mesh cannot degrade *in vivo* while simultaneously remaining effective in some way for some length of time, and (iii) degradation cannot occur in the short-term. Yet, Dr. Pulliam does not address the validity or bases of these presuppositions, thereby implicating the validity and reliability of the hypothesis itself. As Dr. Pulliam fails to identify or explain the basis, process or method of the hypothesis upon which her opinion relies and, similarly, fails to explain the gaps and presuppositions inherent in said hypothesis, Dr. Pulliam's methodology is unreliable. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.").

C. Polypropylene Best Material Available

Within the cytotoxicity and degradation section of her report, Dr. Pulliam also opines that "[t]o date, polypropylene is the best available material for slings." Ex. B, Expert Report at 15. Dr. Pulliam is unqualified to render this opinion, but even if qualified, this opinion is unreliable. For the sake of brevity, Plaintiffs incorporate by reference their qualification and reliability arguments in Sections A and B, *supra*.

Nevertheless, in addition to the qualification arguments in Sections A and B, *supra*, Dr. Pulliam's own testimony establishes that she is unqualified to render this opinion. Indeed, Dr.

Pulliam testified that: she thinks the only difference in the material used across all polypropylene mesh devices, irrespective of manufacturer, is that the material may be woven or knitted at greater or smaller interstices, Ex. D, Pulliam Dep. Tr. at 211:2-14 ("Q. Yeah, just are there different types of it? I mean, not all polypropylene mesh devices are the exact same material? A. So they're all made of polypropylene. . . . They're all made of polypropylene. But they may be woven or knitted at greater or smaller interstices, and so I think there are different types of mesh in that context, but they're all made of the same thing, polypropylene.") (objection omitted); she does not know how many grades there are of polypropylene, *id.* at 216:12-15; she does not know whether Ethicon slings are made with the same grade of polypropylene as Boston Scientific slings, *id.* at 213:17-23; she does know the type of polypropylene pellets used in the TVT mesh, *id.* at 214:11-17 ("Q. Okay. Do you know the type of pellets -- polypropylene pellets that make up the Ethicon TVT device? [A.] There are pellets that are used to make the Ethicon TVT, but those pellets aren't available to me in my patient care.") (objection omitted); she has never examined the pellets, neither under a microscope nor otherwise, *id.* at 214:19-215:3; and, she does not know what antioxidants are in TVT and TVT-O, and is unable to name even one such antioxidant, *id.* at 211:24-212:3; 216:17-217:1. Moreover, Dr. Pulliam's testimony establishes that she is not an expert in biomaterials or polymer science.

> Q. Are you a biomaterials expert?
> A. I think I'm a biomaterials expert to the extent that it's required of me for the purposes of informing my urogynecologic patient care. In other words --
> Q. What does that mean?
> A. What that means is that I need to understand enough about biomaterials to make good choices for patient care.
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> Q. Are you an expert in polymer science?
> A. Again, I'm only an expert in polymer science as it pertains to the care of my patients.
> Q. What does that mean?

> A. That means that when I review the medical literature, one of the things I want to know is, are the devices that I'm using safe and effective. And do they cause any problems that can be attributable to the type of tissues or items that we're using. And in my review of the literature, I don't see anything that I'm concerned about with regard to either TVT or TVT-O.

Id. at 213:25-214:10; 215:13-216:3 (objections omitted). Understanding just enough to make good decisions for her patients does not render Dr. Pulliam qualified to opine to matters squarely in the domain of biomaterials and polymer science, such as polypropylene being the best available material for slings. Lastly, besides implanting different types of mesh products in different patients, she has never tested different mesh materials for the treatment of stress urinary incontinence. *Id.* at 217:3-21.

Regarding reliability, in addition to the incorporated arguments in Sections A and B, *supra*, Dr. Pulliam did not cite or reference any article or study supporting her conclusion that polypropylene is the best available material to date, she has never performed any tests or experiments to come to this conclusion, and she has never submitted any relevant work to peer review. Dr. Pulliam's opinion is a bare conclusion without reliable support. Thus, this *ipse dixit* should not survive *Daubert*. *See Konrick*, 2016 WL 439361, at *5 ("[A]n expert's conclusions must be connected to existing data by more than the mere say-so of the expert.").

In sum, Dr. Pulliam's above testimony, in addition to the incorporated arguments in Sections A and B, *supra*, establish that Dr. Pulliam is unqualified to opine that polypropylene is the best available material for slings, but even if qualified, the opinion is unreliable and, arguably, *ipse dixit*.

II. Opinions regarding fraying and particle loss should be excluded because such opinions are beyond her expertise and are unreliable.

A. Curling or Fraying

Dr. Pulliam seeks to opine that curling or fraying of the edges of TVT and TVT-O does not occur when the devices are "used under normal conditions with normal placement technique." Ex. B, Expert Report at 15. Dr. Pulliam is not qualified to render this opinion, but even if qualified, this opinion should still be excluded as unreliable. For the sake of brevity, Plaintiffs incorporate by reference their qualification and reliability arguments in Sections I.A-C, *supra*.

B. No Adverse Clinical Effects of Particle Loss

Dr. Pulliam also offers the related opinion that even if fraying and particle loss occurs in mechanically cut TVT, there are no adverse clinical effects because such particles would be composed of Prolene and Prolene sutures have been used safely for decades. *Id.* Dr. Pulliam is not qualified to render this opinion, but even if qualified, this opinion should still be excluded as unreliable. For the sake of brevity, Plaintiffs incorporate by reference their qualification and reliability arguments in Sections I.A-C, *supra*.

In addition to the incorporated reliability arguments, the basis for this opinion is not reliable scientific methodology, but rather, "[Dr. Pulliam's] own experience[and] the fact that polypropylene sutures have been present in surgery for decades." Ex. D, Pulliam Dep. Tr. at 160:12-14. Dr. Pulliam's personal experience is unreliable, however, as: she has never documented whether she was implanting a TVT laser cut or mechanical cut beyond what the specific device itself reflects in the medical records, *id.* at 127:14-22; she does not know how many laser cut versus mechanical cut TVT devices she has implanted, *id.* at 127:23-128:2; at the time of each implantation, she did not know whether the device was mechanical cut or laser cut and such knowledge was not important to her, *id.* at 128:21-129:3; of the five TVT patients who presented with complications, she does not know how many were implanted with mechanical cut TVT, *id.* at 130:13-18; of the five TVT revisions or partial explants she has performed, she does not know

how many were mechanical cut versus laser cut, *id.* at 135:22-25; she has never followed the outcomes – in research, clinical trials, her practice or otherwise – of her patients who had mechanical cut TVT versus laser cut, *id.* at 145:14-22; she does not know whether she has ever seen a direct comparison of laser cut mesh to mechanically cut mesh "in any major study that would be meaningful to [her]," *id.* at 150:21-24; and, she has never examined a histopathological slide involving an explant mechanical cut TVT under a microscope, *id.* at 172:14-19. In other words, Dr. Pulliam cites personal experience – experience her above testimony establishes she does not have – as conclusive support of her own opinion. Thus, this opinion is based on mere speculation and, therefore, the opinion should be excluded as unreliable. *See Oglesby v. GMC*, 190 F.3d 244, 250 (4th Cir. 1999) ("A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods.").

III. Opinions regarding the Instructions for Use should be excluded because such opinions are beyond her expertise and are improper.

Dr. Pulliam's opinions regarding the TVT and TVT-O Instructions for Use ("IFU") should be excluded because Dr. Pulliam is not qualified to proffer such opinions. Dr. Pulliam's own testimony establishes her utter lack of experience in regulatory affairs or product warnings.

> Q. And do you have experience with regulatory affairs or product warnings?
> A. So I'm exposed to product warnings when they become available as a physician. There are new black box warnings and so forth from the FDA and other product warnings that have become available, I've become familiar with.
> Q. Have you ever served as a regulatory or warnings expert in a case?
> A. No, I have not.

Ex. D, Pulliam Dep. Tr. at 231:15-232:3 (objections omitted).[3] Not only has Dr. Pulliam never served as a regulatory or warnings expert, but her status as a physician is her sole exposure to

[3] Although Dr. Pulliam cites to, and applies, the Code of Federal Regulations throughout this section of her report, she testified that she does not know what "CFR" stands for. *Id.* at 230:25-231:11.

regulatory affairs or product warnings. Moreover, it is not even clear whether Dr. Pulliam ever referenced or read the IFUs prior to being retained in this litigation.[4]

> Q. Is [the IFU] something that also was a basis or a knowledge base for you in terms of using TVT or TVT-O in a patient? Is that something you relied upon and turned to?
> A. Not particularly, no.
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> Q. Have you ever -- at some point in your career, did you take the time to read Ethicon's IFU?
> A. Yes. I've read at least portions of it in my career.

Id. at 85:21-25; 154:24-155:4 (objection omitted). Despite her own admissions regarding her lack of relevant experience, Dr. Pulliam intends to opine that the TVT and TVT-O IFUs included all the warnings and potential complications mandated by FDA requirements and statute, as discussed in the paragraph below. In short, Dr. Pulliam does not have the "knowledge, skill, experience, training, or education" to opine as to the TVT and TVT-O IFU, Fed. R. Evid. 702, nor does she "possess additional expertise to offer expert testimony about what information should or should not be included in an IFU," *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2017 WL 1175399, at *4 (S.D.W. Va. Mar. 29, 2017) (citing *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015)).

Even if the Court finds Dr. Pulliam qualified, her testimony as to the TVT and TVT-O IFUs warrant exclusion because they are riddled with legal conclusions and are, thus, improper expert opinions. Indeed, the very first sentence of the IFU section states that Ethicon was in compliance with FDA requirements. Ex. B, Expert Report at 25 ("Ethicon, *in compliance with FDA requirements*, has developed Instructions for use (IFU), included with each sling.") (emphasis added). Then, Dr. Pulliam states that the instructions included in the IFUs are "[b]ased on guidance

[4] In addition to qualification and reliability, this also implicates the testimony being litigation-driven.

from the FDA." *Id.* Later in the IFU section, Dr. Pulliam outlines the "known risks" of "[r]etropubic and transobturator mid-urethral sling using polypropylene mesh," *id.* at 26, to preface what is quite possibly the most egregious improper testimony.

> The FDA Document 21 C.F.R. 801.109(c), states that risk information for devices used by licensed professionals may be omitted from product labeling if "the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device." This regulation supports my opinions expressed above.

Id. at 27. In other words, Dr. Pulliam seemingly testifies that because all of the risks associated with TVT and TVT-O are common and known risks of any procedure for SUI, even those which do not use mesh, such commonly known directions, hazards, and warnings may be omitted from the TVT and TVT-O IFUs pursuant to 21 CFR 801.109(c). Thus, not only does Dr. Pulliam assert compliance with FDA requirements, but she also applies law to the facts to reach this opinion. When previously confronted with this antithesis of this issue – the assertion of a violation of the FDCA – this Court held that such an assertion is a legal conclusion. *See Eghnayem v. Boston Sci. Corp.*, 57 F. Supp. 3d 658, 697 (S.D.W. Va. 2014) ("[A]sserting a violation of the FDCA is a legal conclusion, not an expert opinion."). Logically, if asserting a violation of the FDCA is a legal conclusion, then asserting or alluding compliance with FDA requirements and federal statute is a legal conclusion. These opinions are legal conclusions and, therefore, must be excluded. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.")

IV. Opinions regarding training and teaching should be excluded, because such opinions are beyond her expertise, unreliable, irrelevant, and improper.

Dr. Pulliam is not qualified to render these opinions because she has never attended or proctored an Ethicon training session for TVT or TVT-O.

> Q. You testified early this morning that you did not attend Ethicon training other than through Dr. Rosenblatt for implantation of the TVT or TVT-O; is that correct?
> A. That's right, not to my recollection.
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> ***
>
> Q. I mean, how do you know anything about Ethicon training for the TVT and TVT-O?
> A. So I recall that what I said was that my own training included my fellowship training and the experience I had with the physicians that were part of the fellowship. But I think also we discussed the fact that I was present at the trainings, some of them, *that may or may not have been Ethicon*, but I certainly attended trainings for slings like this.

Ex. D, Pulliam Dep. Tr. at 247:23-248:2; 248:21-249:4 (emphasis added). Indeed, when further pressed on the matter, Dr. Pulliam admits that she never attended a cadaver lab for TVT or TVT-O. *Id.* at 249:6-21. In sum, as Dr. Pulliam has never proctored or even attended an Ethicon training session for TVT or TVT-O, she is not now qualified to opine on such training.

Dr. Pulliam does not provide the basis for her opinions regarding training and teaching, thereby rendering these opinions unreliable. Dr. Pulliam discusses TVT and TVT-O training in two different sections of her report. The first mention is in the "Ethicon Training" section wherein she discusses what was typically included in a training session and the credentialing process surgeons must undergo. Ex. B, Expert Report at 27. Two pages later, Dr. Pulliam begins a section with the bolded opinion that the TVT and TVT-O are "carefully and thoroughly taught," wherein she states that the devices come with an IFU "to guide the physician in its use, application and awareness and avoidance of complications," "Ethicon provides multiple opportunities for further education," and that the 2011 FDA "warning created additional awareness for the public and surgeons, and has enhanced the responsibility of each surgeon to develop expertise in the placement of mid-urethral slings." *Id.* at 29. Then, Dr. Pulliam summarily concludes that "[f]rom this wealth of information, surgeons are able to meet the expectations of a thorough and accurate understanding of risks, benefits and surgical technique." *Id.* at 29-30. However, in her report, Dr.

Pulliam does not address the substance of the training beyond cursorily listing the possible components of a training session (i.e., webinars, monograph, cadaver lab, etc.), nor does she explain the basis, such as how or why this training and information enables surgeons "to meet the expectations of a thorough and accurate understanding of risks, benefits and surgical technique." Thus, these opinions should be excluded as unreliable. *See Edwards*, 2014 WL 3361923, at *10 (holding that proffered expert opinion regarding the inadequacy of training is "is unreliable because [the expert] fails to describe the basis for his opinion that Ethicon's training was inadequate").

These opinions are also unreliable because Dr. Pulliam relies upon the MAUDE database as an "attest[ation] to the adequacy of training of physicians who perform slings." Ex. D, Pulliam Dep. Tr. at 250:21-22. In her deposition, Dr. Pulliam testified that the low complication rate in the MAUDE database establishes that physicians who perform sling procedures are adequately trained.

> Q. Do you have an opinion as to whether or not providing -- training provided by Ethicon was adequate for the TVT and TVT-O?
> A. So what I would say is that based on the fact that the MAUDE database, which is a broader reporting, also in that Ford/Cochrane review of complications on a national basis, that the complication rate from placing these things, slings, is very low. *And I think that might be one actual clinical factor that attests to the adequacy of training of physicians who perform slings.*

Id. at 250:9-22 (emphasis added) (objection omitted). As such, these opinions are unreliable. *See Mathison v. Boston Sci. Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *18 (S.D.W. Va. May 6, 2015) (excluding as unreliable an opinion that appeared "to be entirely based on data (or lack of data) found in the MAUDE database").

Exclusion is also warranted because these opinions are irrelevant to the issues and unhelpful to the jury. Dr. Pulliam lists what the Ethicon training programs typically included and

details the credentialing process surgeons must undergo prior to being granted surgical privileges. *See* Ex. B, Expert Report at 27. Put simply, a narrative overview of the various components typically included in Ethicon training sessions and of the credentialing process, such as who grants and maintains physician credentialing, is both irrelevant to the issues – i.e., the design of TVT and TVT-O or the adequacy of their warnings – and unhelpful to the jury. *See Wise*, 2015 WL 521202, at *13 ("Relevance under *Daubert* depends on whether 'a valid scientific connection' exists between the expert's testimony and the facts or issues of the case.") (internal citation omitted). Moreover, these opinions are irrelevant and unhelpful to the jury because they rely upon the low complication rate reported in the MAUDE database, as discussed above. *See Mathison*, 2015 WL 2124991, at *18 ("Any opinion based on data collected in the MAUDE database, which acts as an arm of the FDA, is not helpful to the jury and is therefore inadmissible.").

These opinions should also be excluded because they relate to Ethicon's state of mind, corporate conduct, and intent and are, therefore, improper. For instance, in the very first sentence of the "Ethicon Training" section, Dr. Pulliam states "[t]o *facilitate* safety in procedures involving TVT/TVT-O slings, Ethicon offered training programs in placement of TVT slings, beginning in 1999." Ex. B, Expert Report at 27 (emphasis added). Opinions regarding Ethicon's "facilitat[ion]" of safety inherently relates to Ethicon's state of mind, corporate conduct, and/or intent. Similarly, only two sentences later Dr. Pulliam opines to Ethicon's corporate intent by stating that "[p]hysician training offered by Ethicon is *intended* to supplement the surgeon's training and knowledge, and is not a primary source of expertise." *Id.* (emphasis added). Thus, Dr. Pulliam should not be allowed to testify regarding training and teaching because her proffered opinions constitute improper expert testimony. *See, e.g., Huskey*, 29 F. Supp. 3d at 703 ("Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics are not

appropriate subjects of expert testimony because opinions on these matters will not assist the jury."); *In re Fosamax Prods. Liab. Litig.*, 645 F.Supp.2d 164, 192 (S.D.N.Y. 2009) (holding that "testi[mony] as to the knowledge, motivations, intent, state of mind, or purposes" of a corporation or its employees "is not a proper subject for expert or even lay testimony").

V. Opinions constituting legal conclusions should be excluded because such opinions are improper expert testimony.

This Court has repeatedly held that experts may not draw legal conclusions. *See, e.g., In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013). Nevertheless, Dr. Pulliam has offered legal conclusions, such as "[t]hese guidelines and position statements . . . *do not support the idea that TVT/TVT-O is unreasonably dangerous* for its intended use." Ex. B, Expert Report at 25 (emphasis added). All of Dr. Pulliam's legal conclusions must be excluded. *See Mathison*, 2015 WL 2124991, at *3 ("An expert may not state his opinion using 'legal terms of art,' such as 'defective,' 'unreasonably dangerous,' or 'proximate cause.'").

CONCLUSION

For the above reasons, this Court should grant Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Defense Expert Samantha J. Pulliam, M.D.

This the 13th day of April, 2017.

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PLAINTIFFS' STEERING COMMITTEE

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 4 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I hereby certify that on April 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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